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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,006	09/07/2004	Ashok Bhandari	PK4654USW	8775
23347	7590	07/19/2006	EXAMINER	
GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398			RAHMANI, NILOOFAR	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/507,006	Applicant(s) BHANDARI ET AL.	
	Examiner Niloofar Rahmani	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-27, 29-40, 42-52, 54 and 60 is/are pending in the application.
- 4a) Of the above claim(s) 16-27, 29-40, 42-52 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

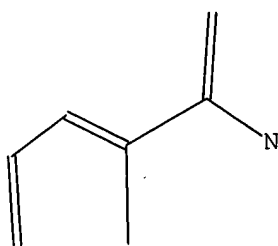
1. Claims 1-14, 16-27, 29-40, 42-52, 54, and 60 are pending. Claims 15, 28, 41, 53, 55-59 are cancelled.

Applicant's election with traverse of group IV in the reply filed on 12/07/2005 is acknowledged. The applicant's traverse is on a ground as followed:

1. In the present case, as evidenced by the restriction itself, claims 1-14 present a unified genus that encompasses each of the groups outlined in the restriction.

Applicant's argument is not persuasive for the following reasons:

1. Compounds of groups I-IV do not share substantially a common core structure essential for the disclosed utility. The common core is



. US 6,608,098 is evidenced that the compounds have the same core and different utility for treating complication of diabetes.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14, and 54 are examined. Claims 16-27, 29-40, 42-52, and 60 remaining subject matter being drawn to the non-elected invention are withdrawn per 37 CFR 1.142(b).

This application contains claims 16-27, 29-40, 42-52, and 60 drawn to an invention nonelected with traverse in remark, filed on 12/07/2005. A

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complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. *Priority*

This application is filed on 09/07/2004, which is a 371 of PCT/US03/05605, filed on 02/24/2003, which claims benefit of 60/362,011, filed on 03/06/2002.

3. *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is rejected because the claims are self-conflicting.

Pharmaceutical composition by definition must be effective yet non-toxic.

Claim 54 is pharmaceutical composition without dosage limitation i.e.

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included both ineffective and toxic amount. It is recommended that "therapeutically effective amount" be incorporated in the claims.

4. **Claim Rejections - 35 USC § 102**

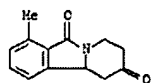
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamley et al. WO 99/01455. Hamley et al. disclosed the instant claimed compounds and compositions on page 20, preparation 11, compound

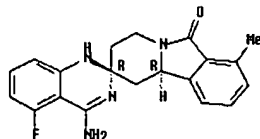
Pyrido[2,1-a]isoindole-2,6-dione, 1,3,4,10b-tetrahydro-7-methyl-



, and

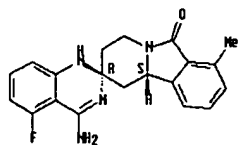
on page 30, Examples 17-18

Spiro[pyrido[2,1-a]isoindole-2(6H),2'(1'H)-quinazolin]-6-one,4'-amino-5'-fluoro-1,3,4,10b-tetrahydro-7-methyl-, (2R,10bR)-rel-



and Spiro[pyrido[2,1-a]isoindole-2(6H),2'(1'H)-quinazolin]-6-one,4'-amino-5'-fluoro-1,3,4,10b-tetrahydro-7-methyl-, (2R,10bS)-rel-

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Therefore, the instant claim is anticipated by Hamley et al.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

07/12 /2006

D. MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625